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**STATE OF DELAWARE**  
**BOARD OF PHARMACY**

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<b>PUBLIC MEETING NOTICE:</b>	<b>BOARD OF PHARMACY</b>
<b>DATE AND TIME:</b>	<b>Wednesday, May 20, 2015 9:30 am</b>
<b>PLACE:</b>	Conference Room A, 2 <sup>nd</sup> Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
<b>APPROVED:</b>	June 17, 2015

**MEMBERS PRESENT**

Susan Esposito, R.Ph., Professional Member, Vice President  
Joli Martini, R.Ph., Professional Member  
Kimberly Robbins, R.Ph., Professional Member arrived at 9:40 am  
Bonnie Wallner, R.Ph., Professional Member  
Hooshang Shanehsaz, R.Ph., Professional Member  
Julia Wheatley, Public Member  
Jay Galloway, Public Member

**MEMBERS ABSENT**

Kenneth Sellers, Public Member, President  
Tejal Patel, PharmD, Professional Member  
David Dryden, Executive Secretary

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

Eileen Kelly, Deputy Attorney General  
Christine Mast, Administrative Specialist III  
Samantha Nettesheim, Pharmacist Administrator  
Michelle McCreary, Pharmacist Compliance Officer

**ALSO PRESENT**

Matt Vendovern  
Jamie Frink  
Zack Green  
Bill Harbestor  
David Leach  
Kapil Patel  
Lakshini Verranedy  
Darrall Heaton  
Kevin Morgan  
Tiffany Sorey  
Maryanne Holzapfel  
Jay C Patel

**CALL TO ORDER**

Ms. Esposito called the meeting to order at 9:30 a.m.

## **REVIEW OF MINUTES**

A motion was made by Ms. Martini and seconded by Ms. Wallner, to approve the meeting minutes for April 15, 2015. The motion unanimously carried.

## **PRESIDENT'S REPORT**

No Report

## **UNFINISHED BUSINESS**

### **Complaint Status**

13-09-11 – Assigned to Hearing Officer  
13-12-11 – Assigned to Hearing Officer  
13-19-11 – Forwarded to Office of Attorney General  
13-01-13 – Forwarded to Office of Attorney General  
13-04-13 – Forwarded to Office of Attorney General  
13-05-13 – Forwarded to Office of Attorney General  
13-06-13 – Forwarded to Office of Attorney General  
13-20-13 – Forwarded to Office of Attorney General  
13-26-13 – Assigned to Hearing Officer  
13-01-14 – Forwarded to Office of Attorney General  
13-03-14 – Assigned  
13-04-14 – Assigned  
13-05-14 – Assigned  
13-06-14 – Forwarded to Office of Attorney General  
13-07-14 – Forwarded to Office of Attorney General  
13-08-14 – Assigned  
13-09-14 – Forwarded to Office of Attorney General  
13-10-14 – Forwarded to Office of Attorney General  
13-11-14 – Forwarded to Office of Attorney General  
13-12-14 – Forwarded to Office of Attorney General  
13-13-14 – Assigned  
13-14-14 – Forwarded to Office of Attorney General  
13-15-14 – Assigned  
13-16-14 – Assigned  
13-17-14 – Assigned

### **Re-Review of Proposal to Deny**

None

### **Proposal to Deny Hearing**

None

### **Re-Review of Tabled Applications**

None

## **Statutory and Regulatory Discussion**

- Practitioner/Pharmacy Ownership. Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Provision for Disciplinary Action. Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Pharmacy Technician Regulation. Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Clarification of §2512(e)(f), Inactive Status, Ms. Kelly will prepare requested changes in bill format for review for the January 2016 Legislative session.
- Review of Crimes Listing - The Legislative Committee meeting has been scheduled for June 17, 2015 immediately following the Board of Pharmacy meeting.

## **NEW BUSINESS**

Ms. Esposito read into the record the following ratifications:

### **Pharmacist and Intern Licensure Approval Ratifications**

**Pharmacist:** A1-0004737 David G. Sherbin  
A1-0004738 Tessina Tressa Thomas  
A1-0004739 Susan Jennifer Dietze  
A1-0004740 Heather H. Wade  
A1-0004741 Ealia Kendra Washington  
A1-0004742 Hajira Ebady  
A1-0004743 Doris Victoria Bertolet  
A1-0004744 Jeffrey E. Paup  
A1-0004745 Kieu-Loan Mau Vu  
A1-0004746 Peris N. Gathura  
A1-0004747 Urvashi Garib-Sohan

A motion was made by Ms. Martini and seconded by Ms. Wallner to approve the ratification of the Pharmacist applications. The motion unanimously carried.

**Pharmacist Intern:** A7-0002389 Sean William Wolf  
A7-0002390 Bethany Rae Sharpless  
A7-0002391 Jillian M. Olmstead  
A7-0002392 Thomas Joseph Crum

A motion was made by Ms. Martini and seconded by Ms. Wallner to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

### **Non-Resident Pharmacy Licensure Approval Ratifications**

A9-0001619 V.V.L.S. Pharmacy Inc., D/B/A Banks Apothecary  
A9-0001620 Genoa, a QoL Healthcare Company, LLC  
A9-0001621 Safeway Pharmacy #4702  
A9-0001622 Leiter's Enterprises Inc. DBA Leiter's Compounding (Sterile)  
A9-0001623 South Miami Pharmacy II Inc. (Sterile)  
A9-0001624 Script Shop Miami, LLC  
A9-0001625 Adler's Pharmacy LTC  
A9-0001626 Crescent Healthcare (Sterile)  
A9-0001627 Creams N' Caps, LLC  
A9-0001628 Advanced Rx  
A9-0001629 Bluegrass Pharmacy of Lexington  
A9-0001630 Heartland Medical, LLC  
A9-0001631 Medical Center Pharmacy  
A9-0001632 Chemistry Rx  
A9-0001633 Petco360 Pharmacy, LLC  
A9-0001634 CFK, Inc. dba The Medicine Shoppe 863  
A9-0001635 SKAR Pharmacy LLC d/b/a Tetra Rx  
A9-0001636 CPA, Inc.  
A9-0001637 Pharmacy Depot, LLC

A motion was made by Ms. Martini and seconded by Mr. Shanehsaz to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

### **Wholesale Distributor Licensure Approval Ratifications**

A4-0001888 RGH Enterprises, Inc  
A4-0002189 Eye Care and Cure Corporation  
A4-0002190 Kuehne + Nagel Inc.  
A4-0002191 AcariaHealth Solutions, Inc.  
A4-0002192 Top Rx, LLC  
A4-0002193 Paragon Enterprises, Inc.  
A4-0002194 Mr. Crash Cart, LLC

A4-0002195 TheraCom, LLC  
A4-0002196 Integrated Commercialization Solutions, Inc.  
A4-0002197 ASD Specialty Healthcare, Inc.  
A4-0002198 Virtus Pharmaceuticals, LLC  
A4-0002200 Alexso Inc.

A motion was made by Ms. Martini and seconded by Mr. Shanehsaz to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000127 Johns Hopkins Pharmaquip, Inc.  
A2-0000128 Dynamic Healthcare Services PA.

A motion was made by Ms. Martini and seconded by Mr. Shanehsaz to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000983 Longneck Pharmacy

A motion was made by Ms. Martini and seconded by Mr. Shanehsaz to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification

None

Outsourcing Facility

AA-0000007 Leiter's Enterprises Inc. DBA Leiter's Compounding

A motion was made by Ms. Martini and seconded by Mr. Shanehsaz to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins arrived at 9:40 am and conducted PIC interviews with:  
Heather Sheridan-Revel, CVS #3738 Rehoboth Beach, De. was on the agenda and did not attend  
Lakshmi Veerareddy, Longneck Pharmacy Millsboro, De.

Consultant Pharmacist Interviews

None

Review of Applications by DAG

None

Review of Hearing Officer Recommendation

Ms. Kelly advised the Board of their responsibilities during the review of the recommendation and read the hearing officer recommendation for Mr. Leonard Bronstein, a licensed Pharmacist in the State of Delaware, for the record. The Board reviewed and discussed the hearing officer recommendations. Although the Board agreed with Mr. Bronstein completing the recommended continuing education 2(a) and no further disciplinary action during the period of suspension 2 (b) of the recommendation there were additional disciplinary actions the Board felt more appropriate. The actions included minimum of 5 years suspension effective this date, \$2500.00 fine, and Mr. Bronstein must petition to appear before the Board for approval of the lifting of his suspension and no further infractions. Ms. Kelly will prepare the final order for the Board to approve and sign during the next meeting scheduled for June 17, 2015.

A motion was made by Mr. Shanehsaz and seconded by Ms. Wheatley to approve the Hearing Officer Recommendation with changes discussed above by the Board. The motion unanimously carried.

A second motion was made by Ms. Robbins and seconded by Mr. Shanehsaz to make the 5 year suspension effective on this date May 20, 2015. The motion unanimously carried.

### Pyxis CII Safe Presentation

Mr. Darrall Heaton, Director of Pharmacy Health South Rehabilitation of Middletown, DE spoke about the Pyxis CII Safe at their location. He provided a handout to all members of the Board, The handout provided visuals of the hardware used in the location at Middletown, De. Mr. Heaton explained the differences in the Pyxis CII Safe utilized in his location. He explained that Mr. David Dryden did a pre-opening inspection of this system at their facility. Mr. Dryden expressed concerns and provided Mr. Heaton with additional requirements that would need to be completed in order to be approved for use. The recommended changes requested were to bolt the safe to the floor because of weight requirements and to remove the carts wheels. The glass/plexi-glass front was allowed due to the system location in the secured pharmacy department.

Ms. Michelle McCreary, Pharmacist Compliance Officer, explained that she was also involved in the site inspection with Mr. Dryden. She explained that the system was inspected and recommended changes were provided to allow the system to be utilized and approved. The location brought the system into compliance by making the suggested changes to the system. Mr. Dryden asked Mr. Heaton to share their system with the Board to make them aware of their pharmacy set up and to make the Board aware.

### COMMITTEE REPORTS

**Legislative** – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

The committee requested to meet on June 17, 2015 immediately following the meeting.

**Continuing Education** – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

**Consumer Affairs** – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

**Professional Liaisons** – Kim Robbins and Tejal Patel:

Ms. Robbins reported there was a Delaware Pharmacist Society convention held in May 2015 and there were approximately 75 in attendance. Ms. Robbins expressed that there were numerous Continuing Education CE's available throughout the convention.

**Controlled Substance Liaisons** – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

No Report

**Patient Safety Committee** – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

Ms. McCreary, Chair reported there was a meeting held in May. The committee determined that no changes would be necessary to the Patient Counseling regulations. This agenda item was requested to be removed from the agenda for the next scheduled meeting on June 17, 2015.

### COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

**USP 795 & 797 Committee** – Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Shanehsaz reported that the FDA is asking for MOU's from each state. Mr. Shanehsaz stated some discussions were related to compounding pharmacies and inspections. He suggested that all out of state pharmacies that provide compounding and are applying for licensure in Delaware be required to provide a current inspection completed by the National Association of Boards of Pharmacy (NABP) prior to licensure to ensure that they are USP 795 & 797 are compliant. Ms. Mast informed the Board that access to NABP, Verified Pharmacy Program (VPP) service was available to participating Boards and this service provides access to inspections completed by NABP. This is currently being utilized and reviewed by the Board Secretary and added to the corresponding pharmacies file if licensed in Delaware. Ms. Mast explained that out of state pharmacy applications are required to provide a copy of the most recent inspection report as part of the application process. Mr. Shanehsaz suggested that all out of state compounding pharmacy applications and renewal applications should be required to be inspected by NABP. Ms. Mast expressed that on the renewal applications a question could be added for the pharmacy to attest to having completed an inspection. If they answer no then a hold is placed and further action can be completed. Ms. Kelly suggested keeping this on the agenda for further discussion.

**Collaborative Care Committee** – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

No Report

### **BOARD CORRESPONDENCE**

Mr. Dryden provided handouts on the following:

NABP, "Consumer Education, Awareness Key to Combating Rogue Online Drug Seller".  
Omeros Corporation, "FDA-Approved Use of Omidra with Ophthalmic Irrigation Solution"

### **EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim**

There is no Executive Secretary report.

Ms. Nettesheim reported that she has been assisting the investigations team with ongoing inappropriate use of the Prescription Monitoring Program (PMP) which is a felony.

Ms. Nettesheim also reported that there will be an upgrade scheduled in the near future for the PMP software. She stated that the upgrade will include some updating to the look and feel of the program and should be more user friendly for the pharmacist. Providers will have access to their own DEA provider look up. This will provide them the ability to do a reverse PMP data report that will allow them to see all patients they have prescribed for. The benefit is that they can easily identify any stolen prescriptions.

Ms. Nettesheim stated she is currently working on linking the PMP data to the states overdose death data for 2012. These would be patients that only have accidentally overdosed. This information will not include suicide deaths; patient data supports most suicide deaths occur in combination with an illicit drug.

Ms. Nettesheim also stated that data reflects that Delaware is #1 in extended release opioid use. This is not a useful indicator of misuse. Delaware also has a high incidence rate of cancer. This correlates to the higher rate of use of extended release opioids. More information on overdose death data will be helpful.

Ms. McCreary reported the following inspections were completed:

- 10 Routine Inspections
- 1 DEA assisted inspection at the Delaware Emergency Management Association (DEMA) location
- 2 New Opening Inspections
- 4 Investigations

### **NEWSLETTER UPDATES**

The most current newsletter was distributed on or around May 4, 2015.

### **OTHER BUSINESS BEFORE THE BOARD**

None

### **PUBLIC COMMENT**

Mr. Robbins announced that DPAC is doing a memorial run in memory of "Don Holst" on June 28, 2015 in Smyrna Park in Smyrna, DE.

### **NEXT SCHEDULED MEETING**

The next meeting is scheduled for June 17, 2015 at 9:30 Am., Conference Room A 2<sup>nd</sup> floor.

### **ADJOURNMENT**

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Martini, seconded by Mr. Galloway at 11:00 am.

Respectfully submitted,



Christine Mast  
Administrative Specialist III  
Liaison, Board of Pharmacy